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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/782,435

02/18/2004

Pramod B. Mahajan

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03/10/2006

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/782,435

Applicant(s)

MAHAJAN, PRAMOD B.

Examiner

Medina A. Ibrahim

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 10/05 in reply to the Office action of 04/07/05 has been entered. Claims 1-27 are pending and are examined.

All previous objections and rejections not set forth below have been withdrawn in view of Applicant's amendment and/or upon further consideration.

Claim Rejections - 35 USC § 112

Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide comprising SEQ ID NO: 4, a recombinant expression cassette comprising said polynucleotide, host cell/plant transformed with said polynucleotide and a method of transforming plant/cell with said polynucleotide, does not reasonably provide enablement for an isolated polynucleotide having at least 80%, 85%, and 90% sequence identity to SEQ ID NO: 3 and encoding a polypeptide having RuvB activity, or nucleic acid sequences encoding polypeptides having at least 80%, 85%, and 90% sequence identity to SEQ ID NO: 4 and having RuvB activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record as set forth in the last Office action of 04/07/05. Applicant's arguments filed 10/05/05 have fully considered but are not persuasive.

Art Unit: 1638

Applicant reiterates that polynucleotides having at least 80%, 85%, and 90% percent of sequence identity and encoding polypeptides having RuvB activity are disclosed in the instant specification, and that the polynucleotides could be made and used by one of skill in the art at the time of filing without undue experimentation.

Applicant provides sequence alignment of the disclosed sequences with sequences from WO 2004/0030313 having a RuvB activity in plants. Applicant, therefore, asserts that the disclosed full-length polynucleotides from corn and the identified conserved domains as well as the teaching of the prior art regarding other RuvB homologues and assays for testing RuvB activity are sufficient to enable one skilled in the art to practice the full scope of the claims. Applicant, therefore, requests that the rejection be withdrawn.

These are not persuasive because the scope of the nucleic acid or polypeptide sequences having at least 80%, 85%, and 90% sequence identity to SEQ ID NO: 3 or 4 and having RuvB activity is not supported by an enabling disclosure. The specification doesn't teach which region in the full-length sequence is sufficient to encode a functional polypeptide having the desired biological function. MPEP and supporting case law clearly indicate that the disclosure must contain sufficient guidance to enable a person skilled in the art to carry out the invention commensurate with scope of the claims. That has not been done in the instant specification as stated in the last Office action.

The specification discloses five unmodified full-length sequences and the specification merely provides general guidance on methods for altering single amino

Art Unit: 1638

acid or conservative amino acid substitutions in given nucleotide/protein sequence to produce variants. However, the specification provides no specific guidance as to where and which modifications would allow SEQ ID NO: 3 retain RuvB activity.

While determination of sequence identity and assays of testing protein activity are well within the level of one skilled in the art, specific guidance are required to modify SEQ ID NO: 3 so that a nucleic acid sequences having both the desired structural and functional characteristics can be obtained. One skilled in the art would have to make all possible nucleotide substitutions and deletions in SEQ ID NO: 3, and test all nucleotide sequences that meet the structural limitation to determine which also meet the functional limitation. One would also have to evaluate the ability of the claimed variants to affect DNA repair protein or integration of a desired DNA into a plant genome. These tests are considered excessive and undue.

Regarding the WO 2004/0030313 reference, it is noted that the publication date of the reference is after the filing date of the instant application, and cannot be relied upon for enablement support. The state of the art existing at the filing date of the application is used to determine whether a particular disclosure is enabling as of the filing date. The MPEP 2164 (05) states that publications dated after the filing date providing information publicly first disclosed after the filing date generally cannot be used to show what was known at the time of filing. See also *Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1325-26 (Fed. Cir. 2004) which teaches that "a patent document cannot enable technology that arises after the date of application". In re Budnick, (537 F.2d 535, 538, 190 USPQ 422, 424 (CCPA 1976)

Art Unit: 1638

states "(i)n general, if an applicant seeks to use a patent to prove the state of the art for the purpose of the enablement requirement, the patent must have an issue date earlier than the effective filing date of the application.

Therefore, in view of the reasons discussed above and in the last Office action, the claimed invention is not enabled throughout the broad scope.

Written Description

Claims 1-27 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the last Office action of 04/07/05. Applicant's arguments filed 10/05/05 have fully considered but are not persuasive.

Applicant argues that the instant specification describes four full-length nucleic acid sequences from maize sharing 87-100% of sequence identity and further describes conserved domains, and provided guidance for amino acid substitutions. Applicant

Applicant's arguments are not persuasive because the rejected claims are not limited to the disclosed four full-length sequences which are all from a single plant species. The scope of the claims encompasses sequences from any sources having 80-90% sequence identity and having RuvB activity. The instant specification does not describe any modification to the disclosed sequences that resulted in a polynucleotide having both structural and functional properties as recited in the claims. The instant specification provides general guidance of sequence modifications, but does not provide

Art Unit: 1638

guidance for how to produce the claimed specific sequences. In addition, the disclosed conserved domains are not unique to RuvB but are common to all DNA repair proteins, and do not constitute a substantial portion of the genus of the claims. Therefore, the disclosed sequences are not representative species of the claimed genus. Therefore, in view of the above and in the last Office action, the claimed invention is not adequately described.

Double Patenting

Claims 1-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6, 706, 949. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in both the application and patent are directed to the nucleic acid sequence of SEQ ID NO: 3 or sequences having % identity thereof, a recombinant expression cassettes, host cells, and transgenic plant comprising said nucleic acid sequence, and a method for modulating the level of RuvB in a plant. This rejection is repeated for the reasons of record as set forth in the Office action mailed 08/25/04 and 04/07/05. In the response of 10/05/05, Applicant has not addressed this rejection. Therefore, the rejection is maintained.

Remarks

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571)

Art Unit: 1638

272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

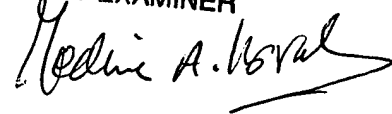
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

3/6/06

MAI

MEDINA A. IBRAHIM
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "Medina A. Ibrahim", with a long, sweeping horizontal stroke at the end.